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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/733,135

12/11/2003

Charles Joel Arntzen

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22885 7590 09/17/2007  
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DES MOINES, IA 50309-2721

EXAMINER

WORLEY, CATHY KINGDON

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

09/17/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/733,135

Applicant(s)

ARNTZEN ET AL.

Examiner

Cathy K. Worley

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                 |                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                            | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/11/03</u> | 6) <input type="checkbox"/> Other: _____                                                |

### DETAILED ACTION

1. The amendment filed June 20, 2007, has been entered.
2. Claims 1-14 are pending.  
Claims 11-14 are withdrawn.
3. Claims 1-10 are examined in the present office action.
4. Rejections and objections not set forth below are withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

### *Double Patenting*

6. Claims 1-10 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 14 of U.S. Patent No. 5,792,935, issued on Aug. 11, 1998, for the reasons of record stated in the previous Office Action mailed on Jan. 18, 2007. The Applicant's arguments in the response filed on June 20, 2007, were fully considered but were not found to be persuasive.

The instant claims are drawn to a method of producing an immunogenic composition, wherein said method comprises the steps of transforming a plant with a nucleic acid encoding a recombinant viral immunogen, and producing from said plants said composition.

Claims 14 of U.S. Patent No. 5,792,935 (herein after the '935 patent) is drawn to a method for producing a transgenic Musa plant expressing a pharmaceutical protein, including the hepatitis B surface antigen and the Norwalk virus capsid protein.

Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1 and 3 of the instant application encompasses methods of producing any viral immunogen in any plant, or of producing an immunogen from any transmissible gastroenteritis virus in any plant; therefore, claim 14 of the '935 patent encompasses a species of the genus encompassed by the instant claims (ie. hepatitis B is one viral immunogen and Norwalk capsid protein is an immunogen from one transmissible gastroenteritis virus; and a Musa plant is one kind of plant). Because a species anticipates the genus, claim 14 of the '935 patent anticipates claims 1 and 3 of the instant application.

The remaining limitations in the instant claims 2 and 4-10 that do not appear in the issued patent are obvious in view of the prior art.

The Applicant argues that the prior art does not teach each element of the claim under consideration (see paragraph bridging pages 23-24 of the response), and that, specifically, it does not teach expressing the recombinant viral immunogen at a level that elicits an immunogenic response upon oral administration (see second paragraph on page 24 of the response).

This is not persuasive, however, because the '935 patent teaches the use of the rice actin 1 promoter and the use of the cauliflower mosaic virus 35S promoter which are both known in the art to drive constitutively high levels of expression. Furthermore the instant claims do not include any specific concentration, required, nor do they include any strength of immune response required; therefore, even if a weak immune response is achieved, it would satisfy the instant claims. The method step of selecting those plants that elicit an immune response is an obvious method step in view of the prior art.

The Applicant further argues that the '935 patent is not enabling for the instant invention, and one would not have an expectation of success in eliciting an immune response utilizing the teachings of the '935 patent (see paragraph bridging page 25 of the response).

This is not persuasive, however, because selection of host plants with high levels of expression was well known in the art, and the ability to elicit an immune response is an inherent property of the hepatitis B surface antigen.

The Applicant further argues that the '935 patent has not provided guidance about whether or not the plant requires heating prior to consumption.

This is not persuasive, however, because the fruit of the Musa plant (banana) is typically eaten without heating, and therefore, the immunogen would be delivered in its native conformation.

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7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner is on a variable schedule but can normally be reached on M-F 10:00 - 4:00 with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975.

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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CKW

A handwritten signature in black ink, appearing to read "Stuart F. Baum", is written over a rectangular stamp.

STUART F BAUM, PH.D.  
PRIMARY EXAMINER